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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,466	03/09/2001	Paul D. Taylor	P-408	7041

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EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/802,466

Applicant(s)

TAYLOR ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-11,21,26-28 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-11,21,26-28 and 30-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to an Amendment filed 11/3/03. Claims 3, 12-20, 22-25 and 29 have been canceled. Claims 5, 7, 26, 28 and 32 have been amended. Claims 1-2, 4-11, 21, 26-28 and 30-33 are pending. An IDS filed 11/3/03 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action. The IDS was sent in response to an objection to embedded hyperlinks and to the appearance of three patent applications in the IDS filed 12/3/02. However, the documents listed on the IDS have not been considered, as they are duplicates of the documents in the IDS filed 12/3/02. There are new grounds of rejection herein that were not necessitated by Applicants' Amendment of the claims, and therefore, this rejection is Non-Final.

Specification

The disclosure is objected to because of the following informalities: on page 23, line 24, figure 14 appears to be mistakenly referred to as figure 4. Acetonitrile on page 30, line 25 is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-11, 21, 26-28 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1, 7 and 28 are vague and indefinite in that the metes and bounds of “ a substantial separation” are unclear. The term “substantial” is a relative one not defined by the claim, no single set of conditions is recognized by the art as being “substantial” and because the specification does not provide a standard for ascertaining the requisite degree, the metes and bounds of this claim cannot be established.

Claims 1, 7, 10, 11, 27-28 and 31 are vague and indefinite in that the metes and bounds of “substantially free” are unclear. The term “substantial” is a relative one not defined by the claim, no single set of conditions is recognized by the art as being “substantial” and because the specification does not provide a standard for ascertaining the requisite degree, the metes and bounds of this claim cannot be established.

Claims 7, 10, 26 are vague and indefinite in that the metes and bounds of the term “substantially denatured” are unclear. The term “substantial” is a relative one not defined by the claim, no single set of conditions is recognized by the art as being “substantial” and because the specification does not provide a standard for ascertaining the requisite degree, the metes and bounds of this claim cannot be established.

Claim 20 recites the limitation "method" in claim 20. Claim 20 is cancelled. Also, there is insufficient antecedent basis for this limitation in the claim.

Claims 30-32 are vague and indefinite in that the metes and bounds of the term “stabilized” are unclear. The term “stabilized” is a relative one not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree of stability such as how “stable” the RNA must be or what conditions or criteria are used to ascertain the “stability” of the RNA.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-6, 11, 21, 26, 27, 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Gjerde (WO 98/56798; filed December 17, 1998) provided by applicant, see entire reference. **This rejection is maintained for reasons of record in the office action filed 6/3/03 and restated below.**

Gjerde et al teach separation of polynucleotides by MIPC wherein multivalent cations are removed from all aspects (page 3, line 17-19). The separation media can be silica and support non-polar organic polymers or long chain C1 to C24 hydrocarbon groups bound to inorganic substrate (page 5, line 1- 17). The separation media has an average diameter of 1-100 microns (page 3, line 23). The present invention can be used in the separation of RNA although for purposes of description, DNA is described (page 9, line 21) and the procedure can be used for batch process (page 5, line 18-25). The method comprises contacting the separation media with eluting solution A, which consists of 0.1 M TEAA pH 7.2 and B, which consists of 0.1 M TEAA and 25% acetonitrile (page 32, line 20-22). The procedure disclosed by Gjerde et al is the same

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as that recited in the instant claims and taught in the instant Specification. Therefore, and absent evidence to the contrary, it would reasonably be expected to yield RNA that is substantially free of agents capable of catalyzing degradation of RNA. Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Claims 1-2, 4-6, 11, 21, 26, 27, 30-33 are rejected under 35 U.S.C. 102(e) and 102(a) as being anticipated by Gjerde (US 5,972, 222; filed May 18, 1998 and published October 26, 1999) provided by applicant, see entire reference. **This rejection is maintained for reasons of record in the office action filed 6/3/03 and restated below.**

Gjerde et al teach separation of polynucleotides by MIPC (column 3, line 15-17) multivalent cations are removed from all aspects (column 2, line 43-45). The separation media can be silica and support non-polar organic polymers or long chain C1 to C24 hydrocarbon groups bound to inorganic substrate (column 2, line 63 to column 3, line 2 and column 16, line 40). The separation media has an average diameter of 1-100 microns (column 2, line 31). The present invention can be used in the separation of RNA although for purposes of description, DNA is described (column 5, line 11-20) and the procedure can be used for batch processes (column 3, line 22). The method comprises contacting the separation media with eluting solution A consists of 0.1 M TEAA pH 7.2 and B which consists of 0.1 M TEAA and 25% acetonitrile

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(column 14, line 45-67 and column 15, line 65 to column 16 line 10). The procedure disclosed by Gjerde et al is the same as that recited in the instant claims and taught in the instant Specification. Therefore, and absent evidence to the contrary, it would reasonably be expected to yield RNA that is substantially free of agents capable of catalyzing degradation of RNA. Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Claims 1-2, 4-6, 11, 21, 26, 27, 30-33 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Gjerde et al (US 5,986,085; filing date April 24, 1998 and publication date November 16, 1999) provided by applicant. see entire reference. **This rejection is maintained for reasons of record in the office action filed 6/3/03 and restated below.**

Gjerde et al teach a batch process for obtaining polynucleotides from a mixture of polynucleotide fragments (abstract) such as RNA (column 3, line 24-36). A counterion such as TEAA is preferred (column 3, line 37-43). Multivalent cations are removed from all aspects (column 2, line 43-45). The separation media can be silica and support non-polar organic polymers or long chain C8 to C24 hydrocarbon groups bound to inorganic substrate (column 5, line 48- 62). The separation media has an average diameter of 1-100 microns (column 6, line 2). The present invention can be used in the separation of RNA although for purposes of description, DNA is described (column 5, line 11-20) and the procedure can be used for batch process

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(column 3, line 22). The method comprises of contacting the beads and polynucleotides with and then contacting the separation media with eluting solution such as 0.1 M TEAA pH 7.2 and a gradient of 33%-55% acetonitrile (column 10, line 65-67). The procedure disclosed by Gjerde et al is the same as that recited in the instant claims and taught in the instant Specification.

Therefore, and absent evidence to the contrary, it would reasonably be expected to yield RNA that is substantially free of agents capable of catalyzing degradation of RNA. Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Claims 1-2, 4, 6-10, 21 and 30-33 rejected under 35 U.S.C. 102(a) as being anticipated by Oefner (US 6,453,244 B1), see entire reference. **This is a new rejection.**

Oefner teaches elution of RNA with a mobile phase containing an ion-pairing reagent and organic solvent under denaturing conditions such as heat or chemicals (see e.g. abstract). The solid support is comprised of silica and the mobile phase is comprised of TEAA and acetonitrile (see e.g. column 4, lines 7-29). Denaturing conditions include temperatures up to 70°C (see e.g. column 4, line 46-53). The separation media has an average diameter of 1-100 microns (column 11, line 24-25), the concentration of TEAA is about 0.05 to 1.0 Molar and about 25% acetonitrile (see e.g. column 12, line 31-55). The present invention can be used in the separation of RNA (see e.g. column 13, line 1-20) and the procedure can be used for large numbers of samples to be

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analyzed (see e.g. column 14, line 40-48). The procedure disclosed by Oefner et al is the same as that recited in the instant claims and taught in the instant Specification. Therefore, and absent evidence to the contrary, it would reasonably be expected to yield RNA that is substantially free of agents capable of catalyzing degradation of RNA. Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Claims 1-2, 4, 6-10, 21 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Joachimiak (ABRF News, December 1992). **This is a new rejection.**

Joachimiak teaches large-scale purification of RNA on columns using non-polar silica separation medium (i.e. C18 or C8). For separation, silica gels are used in the presence of ion-pairing reagent and organic solvent such as 0.1 M TEAA in an acetonitrile gradient (see e.g. page 3, paragraph 1-2). Denaturing conditions include temperatures up to 60°C or 7M urea or high pH (see e.g. page 3, paragraph 1). The procedure disclosed by Joachimiak is the same as that recited in the instant claims and taught in the instant Specification. Therefore, and absent evidence to the contrary, it would reasonably be expected to yield RNA that is substantially free of agents capable of catalyzing degradation of RNA. Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed

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products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Claims 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonham and Danielpour (Biotechniques Vol 21 (1), 1996), see entire document.

Bonham and Danielpour teach the isolation of RNA that is stable (see e.g. page 60, column 1 paragraph 2). The sample is devoid of Rnase inhibitors.

Response to Arguments

Applicants have stated that the specification has been amended to correct errors. The amendments to the specification were not received with the amendment filed 11/3/03.

Applicants traverse the claim rejections under 35 USC 102(e) as anticipated by Gjerde WO 98/56798, 5,972,222 and 5,986,085 on page 12-15 of the amendment filed 11/3/03.

Applicants argue that the present invention and the preceding recited inventions are commonly assigned to Transgenomic Inc and therefore cannot be considered to be the work of another but if the same entity. Specifically, applicants recite the MPEP 715.01(b) as teaching that in an application filed after November 29, 1999 under 35 USC 102(e)/103 using the reference, a showing that the invention was commonly owned is sufficient to overcome the rejection.

Applicant's arguments filed 11/3/03 have been fully considered but they are not persuasive. The argument that a reference used as a rejection under 102(e)/103 is not germane as

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the outstanding rejection is not a 102(e)/103 but a 102(e) rejection. As such it is not governed by the same requirement as a 102(e)/103 rejection.


Conclusion

Claims 1-2, 4-11, 21, 26-27 and 30-33 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571) 272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


GERRY LEFFERS
PRIMARY EXAMINER

Maria B Marvich, PhD
Examiner
Art Unit 1636

January 27, 2004